

**Santamauro, Jon**

**From:** NORMAN\_DOUGLAS@Lilly.com  
**Sent:** Friday, April 27, 2001 3:11 PM  
**To:** scpcomments@uspto.gov  
**Cc:** NORMAN\_DOUGLAS@Lilly.com  
**Subject:** Comments of the National Association of Manufacturers



NAM Comments -  
Final.doc

Dear Mr. Santamauro,

In response to the notice published on March 19, 2001, in the Federal Register (66 Federal Register 15409 - 15411), attached please find the comments of the National Association of Manufacturers.

Thank your for your consideration in this matter,

Douglas K. Norman  
Chair, Intellectual Property Subcommittee  
The National Association of Manufacturers  
1331 Pennsylvania Avenue, NW Suite 600  
Washington DC 20004-1790

(317) 276-2958

# **National Association of Manufacturers**

## **Comments on the International Effort to Harmonize the Substantive Requirements of Patent Laws**

In a notice dated March 19, 2001, (66 Federal Register 15409 - 15411) the Acting Undersecretary of Commerce for Intellectual Property and Acting Director of the United States Patent and Trademark Office requested public comments on the International Effort to Harmonize the Substantive Requirements of Patent Laws. The National Association of Manufacturers (NAM) is pleased to present the following comments in response to that request.

The National Association of Manufacturers (NAM) is a voluntary business association of more than 14,000 member companies (including more than 10,000 small and mid-sized manufacturers) and 350 member associations serving manufacturers and employees in every industrial sector and all 50 states. The NAM is the nation's largest and oldest multi-industry trade association. This broad based constituency enables the NAM to speak affirmatively about changes that can, and should, be made to the international patent system to make it more efficient and cost-effective.

The NAM applauds the United States Patent and Trademark Office for returning to its efforts to seek greater worldwide patent harmonization. While there are many individual reforms that could be enacted to better harmonize US and other patent systems, the NAM advocates a stance that would bring about a fully harmonized patent treaty that could act as the basis for reforming the patent systems in all member states. For instance, the NAM is supportive of a treaty that would dispose of the US "first-to-file" system and the "best mode" requirement, but such a treaty should also address the lack of a meaningful "grace period" and the demand for "industrial applicability" found particularly in the European Patent Office. Only through a unified approach to reach a final draft treaty will the interests of users of a harmonized patent system be attained.

The *Federal Register* Notice of March 19, 2001, requested that all comments be provided on each individual subject and that each item be numbered according to the paragraphs in the Notice. The following comments of NAM are therefore set forth in the manner required by the Notice. However, the NAM urges the parties negotiating on behalf of the United States to bring forward a broad draft treaty as soon as possible, regardless of whether all of the individual subjects of the Notice are included in the draft treaty. *The key component of harmonization efforts should be the formation of a treaty whereby US inventors could receive meaningful cost savings along with a more efficient procedure for obtaining and enforcing patent rights throughout the world. Any draft treaty should therefore eliminate many of the complexities currently found in the patent statutes of the United States and in the systems of other member countries.*

The NAM would most specifically advocate the production of a draft treaty that could be used as a prototype patent statute within all signatory states. The NAM advocates that the draft treaty contain a clear, comprehensive and definitive statement of all substantive requirements for patentability of any subject matter available for patenting. The draft treaty should include provisions calling for publications of all patent applications within a specific time period after filing of the priority documents and specific provisions related to the treatment of these publications as prior art. In addition to an exhaustive set of requirements for patent examination, the draft treaty should also include provisions related to post-grant, third party patent oppositions, appeals and mechanisms for claim interpretation. Finally, the draft treaty should contain provisions whereby decisions of patent offices within any signatory country will be given full faith and credit in the patent offices of other signatory countries. In effect, this entails mutual recognition of the patent examination in the signatory countries.

## PTO Issue 1

“As to priority of invention, the United States currently adheres to a first-to-invent system. The remainder of the world uses a first-to-file rule in determining the right to a patent. Please comment as to which standard is the “best practice” for a harmonized, global patent system. It is noted that while the current draft of the treaty does not address this issue explicitly, it is likely that it will be raised in future meetings.”

**(1) First-to-File System.** The NAM has previously supported a position whereby the United States moved from its current “first-to-invent” system to a “first-to-file system” and currently still strongly favors such a change. Prior to the enactment of the Uruguay Round Agreements Act, NAM had proposed that this change should be made only as part of a broadly based international harmonization agreement whereby other countries also would make improvements in their respective patent systems. With the erosion of the advantages to U.S.-based inventors of the current “first-to-invent” system, we believe that the movement of the United States to a “first-to-file” system now has a greater urgency.

### Comments

A “first-to-file” system is already in place in all other patent systems around the world, thereby requiring many NAM members to organize their patenting efforts to meet this requirement. Thousands of patent applications are filed in the United States each year, yet only a very small percentage (less than 0.1%) ever become involved in an interference contest. Inasmuch as most NAM members already treat their patent portfolios on an international basis, and an exceedingly small number of applications are ever truly involved in a priority contest, the NAM is willing to make this concession to make significant progress towards international patent harmonization.

On a related issue, this proposed change to a “first-to-file” standard in the United States should be joined with an additional change to United States patent law whereby all published applications or granted patents would be accorded an effective prior art date as of their Paris convention date. See Response to PTO Issue 7 – The *Hilmer* Doctrine.

## PTO Issue 2

“As to what inventions may be considered patentable subject matter, the United States currently provides a test of whether the invention is within one of the statutory categories of 35 U.S.C. §101 and within the “useful arts” as expressed in the United States Constitution. The “useful arts” test requires that the claimed invention have a practical application providing a “useful, concrete and tangible result,” see *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998). In contrast, the patent laws of some countries require that the invention provide a “technical contribution” in order to be eligible to be patented. The “technical contribution”

requirement is generally considered to be more restrictive in determining what inventions may be patented.”

**(2) Patent-eligible Subject Matter.** The NAM supports a patent harmonization treaty that would provide patent eligibility for all subject matter that can be shown to provide a “useful, concrete and tangible result.” The NAM does not support any requirement for patent-eligible subject matter to reside in a specific field of “technology,” but believes that patent eligible subject matter should demonstrate some technical contribution above and beyond mere commercial impact. The NAM supports a system whereby all useful subject matter is patentable unless specifically excluded as part of the patent law.

### Comments

A liberal standard for inventions eligible for patenting is supported by the NAM because many members of the NAM manufacture goods that literally encompass “everything under the sun made by man.” While this range of subject matter is afforded patent protection in the United States, the same inventions have been and – in some cases – continue to be denied patent eligibility in other systems. For instance, some NAM members currently use biological processes for the production of human and animal medicines, and such processes should be accorded patent protection given the level of human intervention required to perfect these procedures. Furthermore, the treaty should clarify that there is no subject-matter restriction against otherwise patentable computer-related inventions.

## **PTO Issue 3**

“United States law currently provides for an enablement requirement, a written description requirement and a best mode requirement for patent disclosures. As to enablement, the standard of “undue experimentation” is applied. Regarding written description, United States law requires that the description convey to one of ordinary skill in the art that the applicant had possession of the invention as of the filing date of the application. The best mode requirement under United States law contains both subjective and objective components, with a subjective inquiry related to concealment on the part of the applicant. Standards vary among different patent systems as to disclosure requirements. For example, most other developed countries do not include a best mode requirement, yet many developing countries include or support a best mode requirement that is portrayed by some as a mechanism to compel technology and know-how transfer. The standard for evaluating compliance with such a requirement is an objective one; but, it is objective from the perspective of the examining authority.

**(3) Requirements for Patent Disclosures.** The NAM strongly supports a unified approach to all requirements for patentability, particularly the requirements of what should be in the patent disclosure. Inasmuch as all major patent systems throughout the world have enablement and written description requirements,

**but do not require the disclosure of the best mode, the NAM is supportive of a patent system that does not contain a best mode requirement.**

#### Comments

The patent laws of the majority of industrialized countries contain only wholly "objective" disclosure requirements, *e.g.*, a written description and an enablement requirement. NAM is strongly supportive of harmonization efforts that contain only requirements of this type and oppose permitting a "best mode" requirement, including a "best mode" requirement (a mixed objective/subjective) that is currently found in United States law. Indeed, this was the NAM position taken with regard to the 1992 "Mosbacher Report," (**The Advisory Commission on Patent Law Reform, *A Report to the Secretary of Commerce***, August 1992). This is particularly true given the litigation abuses that have arisen in the United States where the best mode requirement has been a continuous cause of excessive, expensive, and often irrelevant, discovery demands. In addition, the most recent decisions related to the issue in the United States have limited the best mode analysis to what was personally contemplated by the inventor. Such an overly burdensome requirement would not be justified in a harmonized patent system. To promote the social interest in disclosure – the true concern underlying best mode – the United States would be better advised to ensure the adequacy of the written description.

### **PTO Issue 4**

"As to the contents of the claims, some patent systems require the identification of "technical fields" to which the claimed invention relates. This apparently limits, to some degree, the categories of invention to which claims may be directed. There is no such requirement under current United States law."

**(4) Technical Field Identifications. Some patent systems require the identification of the "technical field" to which the claimed invention relates. The NAM sees the identification of the technical field requirement as an overly restrictive and unnecessary formality that does not add any meaningful benefit to the examination or enforcement of the patent claims, or, if invoked as a substantive requirement, is likewise unwarranted.**

#### Comments

The NAM would support any system in which consistency and fairness prevail over rigid and formalistic approaches. The language of the claim should be drafted in a manner that best describes the metes and bounds of the invention, rather than a rigid format that requires recitation of formalities that do not add substance to the construction or interpretation of the claim language. Equally importantly, any requirement for a

“technical effect” merely serves to place needless requirements on products and processes “made by man” that should categorically be deemed eligible for patenting.

### PTO Issue 5

“With regard to the issue of multiple inventions contained in a single patent application, most of the world uses a “unity of invention” standard, which is also contained in the Patent Cooperation Treaty (PCT). For national applications, the United States currently uses a restriction practice based on independence and patentable distinctness between claimed inventions.”

**(5) Unity of Invention.** The NAM advocates the adherence to a “unity of invention” standard for examination of patents under a patent harmonization treaty. This standard has been found to be reasonable and simple to administer in both the European Patent Office and through the Patent Cooperation Treaty. However, no granted claim should be held invalid for an alleged lack of “unity of invention.”

#### Comments

The United States Patent and Trademark Office should be able to reasonably implement the current unity of invention standards found in the PCT in a manner consistent with both the PCT and EPC requirements.

### PTO Issue 6

“United States law currently provides a utility requirement for patentability in 35 USC §101. Utility of an invention must be specific, substantial and credible. Most other patent systems have a requirement for industrial applicability. Industrial applicability is generally considered to be a narrower standard than utility, as it requires that the invention be usable in any type of industry.

**(6) Industrial Applicability.** The NAM supports a system whereby the utility requirement is not bound directly to the concept of industrial applicability.

#### Comments

The utility requirement in the United States holding that the invention must be specific, substantial and credible should be followed to allow the patenting of any invention which is currently and practically useful, unless such use is for an insubstantial purpose or effect. Certain restrictions found in some patent systems denying patentability to specific medical treatments and therapies are too narrow. Furthermore, many NAM members use biological processes for the manufacture of numerous products, and such biological

processes should be accorded eligibility for patenting commensurate with the scope of human invention entailed in the process. *See*, Response to PTO Issue 2.

### PTO Issue 7

“Current discussions in the SCP have indicated a willingness to implement a global priority date as to the prior art effective date of patent applications that are published or granted as patents. United States law now limits the prior art effective date of United States patents and United States patent applications to their effective filing date in the United States. *See In re Hilmer*, 359 F.2d 859 (CCPA 1966) and 35 USC §102(e). Further, United States law currently limits the prior art date as to foreign patent publications to their publication date, although international application publications are available as of their filing date, if published in English. *See* 35 USC §102(e).”

**(7) Global Priority Date.** The NAM supports a treaty whereby patent applications that are published or granted as patents in any signatory state are provided a global priority date as the prior art effective date. This change appears to be inherent in adoption of a “first-to-file” system. Unless undertaken as part of a move to a “first-to-file” system, this change would negate the current effects of the “Hilmer doctrine” which strictly limits the prior art effect in the United States of prior-filed non-US patent applications. NAM, therefore, supports this change as part of its categorical commitment to see the United States adopt a “first-to-file” system..

#### Comments

As an element of the changes that are needed to be made to United States law in adopting a “first-to-file” system, the NAM assumes that the United States will totally remove any residual effects of the *Hilmer* doctrine. This would be accomplished by giving a patent defeating prior art effect to any U.S. patent or U.S. published patent application as of the Paris Convention date, if applicable. Such a patent defeating prior art effect should be for both novelty and obviousness purposes with respect to the “whole contents” of the publication, but not have an immediate “self-collision” effect. *See* Response to PTO Issue 8.

### PTO Issue 8

“United States practice allows patent applications to be considered prior art as to situations of both novelty and obviousness, provided the application is earlier filed and is published or granted as required by 35 USC §102(e). Some other patent systems apply this type of prior art only with respect to novelty, due to concerns of the effect of what may be considered “secret” prior art. Such a novelty-only system, however, may also allow for the granting of multiple patents directed to obvious variations of inventions.”



**(8) Prior Art Effects.** The NAM supports a system whereby the effective global priority date may be used for purposes of both novelty and obviousness.

Comments

In conjunction with the concessions made to the change in United States law related to the “first-to-file” system and, by necessary implication, the *Hilmer* doctrine, any harmonized system should require that the effective global priority date be a bar to patentability both for novelty and obviousness. This is a simple approach, prevents the issuance of multiple, adverse patents with virtually indistinguishable claims, and avoids the creation of a two-tier approach to “prior art” issues that unduly focuses on the differences between novelty and non-obviousness. Such a rule should, however, avoid the “self collision” problems currently seen in the EPC.

### PTO Issue 9

“United States patent law provides a “grace period.” Disclosures by the inventor during the “grace period” do not have a patent defeating effect. Some other systems have an “absolute novelty” requirement such that any disclosures, including those made by an inventor himself, made prior to the date the application is filed, are considered prior art.”

**(9) Grace Period.** The NAM advocates the introduction of a limited grace period into any patent law harmonization treaty thereby allowing a patent to be granted even after a public disclosure by or on behalf of a named inventor or the assignee.

Comments

The length of time allowed for a “grace period” – based on simplicity and the precedent of the Paris Convention year – should be set at one year. In addition, at this time, the grace period should apply only with respect to a disclosure made by or on behalf of a named inventor.

### PTO Issue 10

“Recent discussions at the SCP have indicated a willingness on the part of many member states to eliminate any geographical restrictions that limit the definition of prior art. Currently, United States prior art requirements limit certain types of disclosures to acts within particular geographical limitations, such as the territory of the United States.”

**(10) Geographical Restrictions on Prior Art.** The NAM is willing to accept the elimination of any geographical restrictions that limit the definition of what would constitute prior art.

#### Comments

Given the current state of intellectual exchange via the Internet, everything that is reasonably accessible to the skilled artisan in one jurisdiction can also be accessed in another jurisdiction. A limitation or restriction on the definition of prior art in the Information Age is problematic given that anything known or retrieved from the Internet in the United States can also be known or retrieved by anyone in the world who also has Internet access.

### **PTO Issue 11**

“United States law provides for loss of right provisions, as contained in 35 USC §§102(c) and 102(d), that discourage delays in filing in the United States. Further, 35 USC §102(b) bars the grant of a patent when the invention was “in public use or on sale” more than one year prior to filing in the United States. Secret commercial use by the inventor is covered by the bar in order to prevent the preservation of patent rights when there has been successful commercial exploitation of an invention by its inventor beyond one year before filing. Most other patent systems do not have such provisions.

**(11) Loss of Rights Provisions.** The NAM believes that the interests of simplification of the patent laws justifies elimination of several “miscellaneous” requirements for patentability, including the “forfeiture” under section 102(b), abandonment under section 102(d) and premature foreign patenting under section 102(d).

#### Comments

A major component of any harmonization treaty should be the maintenance of the right to obtain patent protection so long as the acts of the inventor are not publicly accessible to persons of ordinary skill in the art. If the acts of the inventor or the inventor’s agents cause a disclosure of the invention that is reasonably and effectively accessible to persons of ordinary skill in the art, it should be patent-defeating after one year. If the invention is not so accessible, there should no longer be a personal forfeiture. This avoids the complexity and arbitrariness of the “ready for patenting” standard recently set forth in the United States.

## PTO Issue 12

“Current United States novelty practice allows, in limited circumstances, the use of multiple references for the anticipation of a claim under 35 USC §102. These circumstances include incorporation by reference, the explanation of the meaning of a term used in the primary reference or a showing that a characteristic not disclosed in the primary reference is inherent. Some other systems have stricter requirements for the use of additional references as to the determination of novelty.”

**(12) Use of Multiple References to Determine Novelty.** The NAM favors a system whereby any reference used in a novelty attack on a claim should contain all elements of the claimed invention. If other references are needed to determine what a primary reference discloses to a person of ordinary skill in the art, then those other references should be permitted to be used.

### Comments

The classic global definition of novelty-destroying prior art arises from a single reference. Although there have been narrow circumstances in United States law whereby secondary information was considered together with a primary reference to establish the scope of the novelty-destroying subject matter of the single reference, this application of the law of novelty should be recognized, but it should not be extended to produce a pseudo-obviousness standard.

## PTO Issue 13

“United States practice in determining obviousness under 35 USC §103 follows the practice set forth in *Graham v. John Deere*, 383 US 1 (1966), and its progeny. Obviousness determinations vary throughout different patent systems. For example, some provide for a problem-solving approach, requiring the identification of a technical problem to be solved by the invention. There is no such requirement under United States law.”

**(13) Obviousness Analysis.** The NAM advocates an analysis of non-obviousness of patent claims using methodology closely aligned with the traditional United States practice arising from *Graham v. John Deere* and its progeny. The NAM believes that the unduly restrictive and inflexible “problem-solution” approach used by the European Patent Office is unacceptable.

### Comments

Although the European Patent Office insists on a “problem-solution” approach to analyzing the question of inventive step, this pro forma requirement is often burdensome and unworkable, particularly in the biotechnological arts. Any number of processes may

be used to appropriately determine whether an invention is obvious in view of the prior art, therefore the harmonization treaty should not dictate that a single, specific approach be used.

### PTO Issue 14

“Current United States practice limits the filing of multiple dependent claims in 37 CFR § 1.75(c) such that these claims must refer to the claims from which they depend only in the alternative. Further, a multiple dependent claim cannot depend from another multiple dependent claim. Some other patent offices allow for multiple dependent claims without these restrictions.”

**(14) Multiple Dependent Claims. Any procedure that allows for the simple and inexpensive drafting and prosecution of claims is acceptable to the NAM. The NAM is in favor of a treaty that would allow multiple dependent claims that depend from other multiple dependent claims, so long as it is clear that any multiple dependent claim should be construed to include all limitations of the claims from which it depends.**

#### Comments

The NAM's default position on issues of this type, *i.e.*, those that are of relatively secondary importance, is that the freedom of the applicant to claim the invention in the manner of the applicant's choosing is the higher and better solution.

### PTO Issue 15

“There has also been discussion within the SCP regarding the manner in which claims should be interpreted as to validity. It is not clear at this time whether both pre-grant and post-grant interpretation issues will be addressed. However, we are interested in comments with regard to any claim interpretation issues at this time as these issues may appear in future SCP meetings. For example, the United States generally subscribes to a peripheral claiming approach to interpretation in which the language of the claims dominates, although United States law provides that when an element in a claim is expressed as a means or step for performing a function, the claim will be construed to cover the corresponding structure, material or acts described in the specification and equivalents thereof, see 35 USC §112, paragraph 6. Other systems take a different,

centrally focused view of the claimed invention that allows, in certain circumstances, for broader interpretation of the scope of the claimed invention.”

**(15) Claim Interpretation.** The NAM believes that the language of the claim should be the dominating factor in any claim interpretation analysis. Furthermore, applicants should be given an option, for any claim that recites a means or step for performing a function, to be construed to cover either (a) only the disclosed means, *i.e.*, the corresponding structure, material or acts described in the specification and equivalents or (b) all means, *i.e.*, any means in an alleged infringing device that performs the recited function.

#### Comments

The most important aspect of this recommendation lies in the need to guarantee that “means plus function” claims are not unduly or unnecessarily limited simply by what is disclosed in the patent specification. NAM urges that a novel bifurcated approach to “means plus function” claims be considered that would allow applicants to limit claims to a “means for ...” or a “disclosed means for ...”, with only the latter formulation limiting the claim to the disclosed structures or acts in the patent specification and equivalents thereto.

### PTO Issue 16

“With further regards to claim interpretation, the United States currently applies the “doctrine of equivalents” when appropriate in interpreting claims in post-grant infringement cases. The “doctrine of equivalents” has continued to evolve in the United States, especially in view of the recently decided case of *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558 (Fed. Cir. 2000). Furthermore, the European Patent Convention (EPC) was recently amended to provide a more explicit basis for “doctrine of equivalents” determinations in the text of newly added Article 2 of the Protocol on the Interpretation of Article 69 EPC. This doctrine has also been recognized in litigation in Japan. However, some systems do not provide for such equivalents.”

**(16) Doctrine of Equivalents.** The NAM strongly favors a system whereby the Doctrine of Equivalents is favored for the interpretation of claims in a post-grant infringement action.

#### Comments

Although the Doctrine of Equivalents is interpreted under national laws, it is important that any harmonization treaty specifically allow for the use of a standard that does not unduly restrict the claims to a narrow literal construction. On the other hand, the treaty

should also require that the claims are not to be viewed as mere suggestions or guidelines on defining the invention.

### PTO Issue 17

“United States practice now requires that a patent be applied for in the name or names of the inventor or inventors. However, some systems allow for direct filing by assignees. Although the draft treaty text is currently silent on this issue, it may be raised at future meetings.”

**(17) Filing Requirements. The NAM favors a system in which the patent application is filed by the real party in interest, whether that party is the individual inventor, a group of joint inventors or the assignee of the patent.**

#### Comments

Allowing the assignee to file a patent as the “real party in interest” would greatly expedite and simplify procedures for obtaining patent rights under a truly harmonized patent law. Furthermore, for patents (or published applications) to be retrievable by the name of the real party in interest greatly facilitates locating that party where negotiations are desired or licensing is appropriate.

*In conclusion, the NAM supports a global patent harmonization treaty designed to eliminate many of the complex and overly rigid aspects of patent systems around the world. In that vein, the NAM is willing to concede to such a treaty that would eliminate the “first-to-invent” and “best mode” requirements of United States patent law. In so doing, however, the NAM must see that the same treaty also eliminates many various encumbrances found in other countries such as technical field specifications, industrial applicability, subject matter restrictions related to computing, or overly literal claim construction reflected in the lack of an equivalency concept. Of utmost importance is a treaty that would enable inventors of all signatory states to obtain meaningful patent protection in major countries at markedly reduced cost and effort.*

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Douglas K. Norman  
Chair, Intellectual Property Subcommittee  
National Association of Manufacturers  
1331 Pennsylvania Avenue, NW Suite 600  
Washington, DC 20004-1790  
(317) 276-2958

